



25.3800 PCT/Cont. V

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
STEVEN C. CLARK ET AL.)
Application No.: 08/466,308)
Filed: June 6, 1995)
For: RECOMBINANT HUMAN)
GRANULOCYTE MACROPHAGE-)
COLONY STIMULATING)
FACTOR (GM-CSF))
Examiner: Prema Mertz, Ph.D.
Group Art Unit: 1646
Date: July 23, 1998

Assistant Commissioner for Patents
Washington, D.C. 20231

TERMINAL DISCLAIMER

RECEIVED
JUL 29 1998
GROUP 1800

Sir:

Your petitioner, Novartis AG, successor to Sandoz Ltd., a corporation duly represented by the undersigned attorney of record, represents that it is the assignee of the full title and interest in and to the above-identified Application No. 08/466,308, filed June 6, 1995, as evidenced by the deed of Assignment recorded on September 19, 1984 at Reel 4313, Frames 108 and 109.

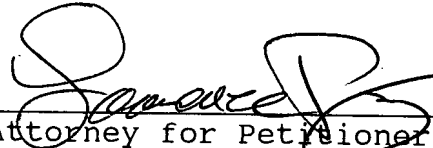
Your petitioner hereby disclaims the terminal part of any patent granted on Application No. 08/466,308 which

would extend beyond the expiration date of the full statutory term of any U.S. Patent issuing from pending U.S. Application No. 08/344,809, filed November 23, 1994, as presently shortened by any terminal disclaimer, and hereby agrees that any patent so granted on Application No. 08/466,308 shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to any U.S. Patent issuing from Application No. 08/344,809, this agreement to run with any patent granted on Application No. 08/466,308 and to be binding upon the grantee, its successors or assigns.

Your petitioner does not disclaim any terminal part of any patent granted Application No. 08/466,308 prior to the expiration date of the full statutory term of any U.S. Patent issuing from Application No. 08/344,809, as presently shortened by any terminal disclaimer, in the event that subsequent hereto such U.S. Patent expires for failure to pay a maintenance fee, is held unenforceable, is found invalid, is the subject of any disclaimer under 37 C.F.R. 1.321(a), has all claims cancelled by a reexamination certificate or is otherwise terminated prior to the expiration of its statutory term as presently shortened by any terminal disclaimer, except for the separation of legal title stated above.

Petitioner's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should be directed to our below listed address.

Respectfully submitted,



Attorney for Petitioner
Lawrence S. Perry
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

F508\A609540\ac

SUBJECT: DECISION ON TERMINAL DISCLAIMERS INFORMAL FORM

DATE: 8-10-98

APPL. S.N.: 081 466 308

TO EXAMINER: P. Hertz

ART UNIT: 1646

M. MONTGOMERY ROOMTIE

MAILROOM DATE 7-24-98

AFTER FINAL YES ☐ NO ☒ NUMBER OF T.D(S). FILED 1

INSTRUCTIONS: I have reviewed the submitted T.D. with the results as set forth below. If you agree, please use the appropriate form paragraphs identified by this informal memo in your next office action to notify applicant about the T.D. If you disagree with my analysis or have questions at all about the acceptability of the T.D., please see me or our Special Program Examiner. THIS MEMO IS AN INFORMAL, INTERNAL MEMO ONLY. IT MUST NOT BE MAILED TO APPLICANT, NOR SHOULD A COPY BE LEFT IN FILE.

☒ The T.D. is PROPER and has been recorded. (See 14.23).

☐ The T.D. is NOT PROPER and has not been accepted for the reason(s) checked below. (See 14.24).

☐ The recording fee of \$ _____ has not been submitted nor is there any pre authorization in the application file to charge to a deposit account. (See 14.26.07)

☐ Application Examiner has not processed T.D. fee. (See fee authorization).

☐ The T.D. does not satisfy Rule 321(b)(3) in that the person who has signed the T.D. has not stated his/her interest (and/or the extent of the interest of the business entity represented by the signature) in the application/patent. (See 14.26 and 14.26.01).

☐ The T.D. lacks the enforceable only during the common ownership clause needed to overcome a double patenting rejection, Rule 321(c). (See 14.27, 14.27.01).

☐ It is directed to a particular claims(s), which is not acceptable since "the disclaimer must be of a terminal portion of the term of the entire patent to be granted". MPEP 1490. (See 14.26, 14.26.02).

☐ The person who signed the terminal disclaimer:

☐ has failed to state his/her capacity to sign for the business entity, (See 14.28).

☐ is not recognized as an officer of the assignee, (See 14.29 and possibly 14.29.01).

☐ No documentary evidence of a chain of title from the original inventor(s) to assignee has been submitted, nor is the reel and frame specified as to where such evidence is recorded in the office. 37 CFR 3.73(b). (See 1140 O.G. 72). **NOTE:** This documentary evidence or the specifying of the reel and frame may be found in the T.D. or in a separate paper submitted by applicant. (See 14.30).

☐ No "statement" specifying that the evidentiary documents have been reviewed and that, to the best of the assignee's knowledge and belief the title is in the assignee seeking to take action. 37 CFR 3.73(b). (See 1140 O.G. 72) (See 14.31).

☐ The T.D. is not signed. (See 14.26, 14.26.3). or 14.26.03 If TD is not signed by all the owners.

☐ Attorney not of record in oath/decl. or a separate paper filed appointing a new or associate attorney. (See 14.29.01).

☐ The serial number of the application (or the number of the patent) which forms the basis for the double patenting is missing or incorrect. (See 14.32).

☐ The serial number of this application (or the number of the patent in reexam or reissue case(s) being disclaimed is missing or incorrect. (See 14.26, 14.26.04 or 14.26.05).

☐ The period disclaimed is incorrect or not specified. (See 14.27, 14.27.2 or 14.27.3)(For Samples 14.27.04 and 14.27.05)

☐ Other: _____

☐ Suggestion to request refund of \$ _____. (See 14.35, 14.36).

☐ **EXAMINER NOTE: IF APPLICATION IS IN CONDITION FOR ALLOWANCE ANY OF THE ABOVE INFORMALTIES MAY BE FAXED IN TO THE GROUP**

FOR SAMPLE TERMINAL DISCLAIMERS AND CERTIFICATES:

☐ Sample of a 1U over a pending application and assignee Certificate (See 14.37).

☐ Sample of a TD over a prior patent and assignee Certificate (See 14.38).

☐ Sample Assignee Certificate under 37 CFR 3.73 (b) (See 14.39)